SOUTHERN AFRICA GLOBAL COMPETITIVENESS HUB

Technical Report: Compilation of a HACCP plan for a fruit concentrate processing plant

Dr. Lucia Anelich

Submitted by:
Chemonics International, Inc.

Submitted to:
Regional Center for Southern Africa,
U.S. Agency for International Development

Gaborone, Botswana

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ACKNOWLEDGEMENTS

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- Mr Bill Hargraves for foremost his friendship and also for his dedication to improving food safety in the SADC region, for the purpose of creating better prosperity for the people in this region.
- Chemonics International Inc and USAID for their support in enhancing food safety, in particular, in the SADC region.
- Mr Trevor Dunlop, General Manager of Letaba Citrus Processors for his support in rendering me with the necessary resources for the periods that I spent at LCP; for making me feel very welcome at all times and his commitment to allocating the necessary resources for the successful implementation of HACCP.
- All members of the HACCP team with whom I worked well, due to their commitment towards the implementation compilation of HACCP at LCP.
- Excellent administrative assistance from the Hub offices in Gaborone, Bostwana.

PURPOSE OF THIS REPORT

This report serves as the final report for the project, “Compilation of a HACCP plan for a fruit concentrate processing facility”, task order 2.4. It contains full details of the project since it began in March 2003 to its completion on 30 June 2003, including all necessary HACCP documentation and records comprising the HACCP plan to be implemented at the facility concerned.

BACKGROUND

Scope of work

The scope of work decided upon between Chemonics International Inc (represented by Mr Bill Hargraves) and Professor Lucia Anelich is set out below:

1. Investigate and select one company in South Africa to introduce HACCP Planning
2. Meet with top management and quality assurance/quality control management to introduce the concept of Hazard Analysis Critical Control Point (HACCP) planning;
3. Determine that pre-requisite programs (PRP) are currently in use – these include Good Manufacturing Practices, Good Health Practices, etc., that they are adequate and effective;
4. Assist this company to implement HACCP plan in accordance with the identified twelve steps as detailed by CODEX ALIMENTARIUS;
5. Facilitate compliance of HACCP plan and record keeping system (but not to include computer program for data collection).

Deliverables

1. Written progress report due at the end of first calendar quarter (March 31)
2. Written Assessment Report for selected factory regarding existing PRPs and their effectiveness at the end of assignment
3. A written Needs Assessment for further HACCP training
4. All documents generated in the Implementation Phase
5. A written HACCP Plan document for the factory

Duration of assignment

The assignment will be for not more than 50 working days beginning February 03, 2003, ending not later than June 30, 2003.

Identification of appropriate facility

A fruit concentrate processing facility by the name of Letaba Citrus Processing (LCP) situated in Letaba (close to Tzaneen) in the Limpopo Province of South Africa is known to Prof Anelich, due to previous contact. This facility processes a variety of fruits into fruit concentrates, which are then sold in bulk, to the fruit juice industry, either in aseptically packaged or frozen form for further processing into a variety of fruit juices. These include pure, aseptically packaged and therefore, heat-treated fruit juices (particularly of the subtropical variety), and different fruit juice blends (usually preserved, by chemical means). In addition, LCP processes orange, lemon and grapefruit juice concentrates, under contract, for the frozen fruit juice market. Approximately 65 000 tons of citrus fruit per season are thus processed and over 10 million litres of subtropical juices, blends and purees are produced. Due to the fact that this facility processes both summer and winter fruits, the plant runs continuously throughout the year, albeit different sections of the plant. A bulk storage capacity of 1.2 million litres with a freezer capacity of seven million litres is available on site, thus enabling the company to maintain strategic stocks between seasons. LCP also has its own water purification system, as water is supplied from the Letaba river – hence the need for appropriate on-site purification and chlorination of the water. LCP currently supplies the local market in South Africa and also exports some product to individual countries in the European Union. It has recently identified possible export opportunities to the USA. However, much pressure is being placed on LCP, locally, but

particularly internationally to implement HACCP. As Prof Anelich was aware of this at the time of discussions around this project, it was decided to approach Mr Trevor Dunlop, the General Manager of LCP with the offer to assist this company in compiling a HACCP plan for a particular process. Mr Dunlop was most interested and it was decided to conduct this project particularly for the aseptic processing plant, thereby covering the production of the following subtropical products:

- Mango puree
- Banana puree
- Guava puree
- Paw-paw.

ASSESSMENT OF FACILITIES AND REQUIREMENTS

Plan of Action

- A plan of action was compiled by Prof Anelich based on her existing knowledge of the company and telephonic discussions with Mr Dunlop (Table 1). This action plan included task, target date and responsible persons and was discussed and accepted on 18 March 2003, between Mr Dunlop and Prof Anelich, with the understanding that the plan is flexible, depending on the time that LCP staff (HACCP team) can spend away from their normal duties, working on the HACCP plan, as well as the availability of funding to upgrade the facilities as needed. In terms of the compilation of the HACCP plan, target dates were met throughout, thus fulfilling the scope of work for this project. This however, was not the case with the compilation of the pre-requisite programmes (PRPs), which was not included in the scope of work, but is nevertheless, essential for HACCP implementation.

Table 1: Action Plan for HACCP for LCP

Recommended step	Recommended target date	Person(s) responsible
Conduct gap analysis where	4 and 5 March 2003	L Anelich (LA)

Recommended step	Recommended target date	Person(s) responsible
shortcomings relevant to the required industry standards are identified.		
A person from LCP has to be identified and appointed to take responsibility for the entire implementation process. This person will also act as communication point between the consultant, management and HACCP team. This person should also act as the HACCP team chairperson and needs to attend an official training course.	By 17 March 2003	T Dunlop (TD)
Review gap analysis report and conduct any further assessment required.	Afternoon of 17 March 2003	LA
Compile PRPs and document all procedures in an acceptable format. Person identified (above), should ensure that these PRPs are implemented without delay, so that any deficiencies can be identified promptly, without unnecessarily holding up progress with the HACCP plan.	17 April 2003	LA, LCP representative (identified above as HACCP team chairperson)
E-mail all PRP documentation to LA.	17 April 2003	HACCP team chairperson
Feedback re PRP documentation.	25 April 2003	LA
Correction of deficiencies identified and verification that adapted PRPs are working.	By 5 May 2003	HACCP team chairperson
Management and HACCP team awareness training. This will include the basic requirements (such as PRPs) for the implementation of a HACCP system with the aim of applying for HACCP Certification, once the plan is implemented.	18 March 2003 – morning session beginning at 08:00.	Presenter: LA TD and as many relevant persons as possible to attend – in particular those that will constitute HACCP team
Discuss, refine (where necessary)	18 March 2003 – afternoon	LA; TD and HACCP

Recommended step	Recommended target date	Person(s) responsible
and approve the implementation action plan as well as role clarification of all concerned.	session	team chairperson as well as any other person deemed necessary by LCP management.
Begin HACCP study (Steps 1-4)		
Step 1 (Assemble team)	18 March 2003 – afternoon session	LA; TD and HACCP team chairperson HACCP team
Step 2 (Describe product)	By 28 March 2003	HACCP team
Step 3 (Identify intended use)	By 28 March 2003	HACCP team
Step 4 (Construct product flow diagram)	By 28 March 2003	
E-mail all documentation re steps 1-4 to LA.	28 March 2003	HACCP team chairperson
Verification of documentation received covering steps 1-4.	31 March 2003	LA
Feedback and Step 5 of HACCP (On-site confirmation of flow diagram).	7 April 2003 (on site at LCP)	LA; HACCP team
Step 6 of HACCP (Conduct Hazard Analysis)	8 – 9 April 2003 (on site at LCP)	LA; HACCP team
Completion of hazard analysis (if necessary)	By 17 April 2003	HACCP team
E-mail hazard analysis to LA.	17 April 2003	HACCP team chairperson
Verification of hazard analysis.	By 25 April 2003	LA
Feedback and steps 7, 8, 9, 10, 11 of HACCP (Determine CCPs, Establish critical limits; Monitoring; Corrective Action, Verification respectively)[1].	5 – 9 May 2003 (on site at LCP)	LA; HACCP team
Complete steps 7-11.	By 30 May 2003	HACCP team

Recommended step	Recommended target date	Person(s) responsible
E-mail all documentation re steps 7-11.	30 May 2003	HACCP team chairperson
Feedback re steps 7-11.	13 June 2003	LA
Final discussion and review of written HACCP plan.	17 – 20 June 2003 (on site at LCP)	LA; HACCP team
Progress report to USAID.	31 March 2003	LA
Final report to USAID.	30 June 2003	LA

[1]: Step 12 of HACCP i.e. Documentation and Record- keeping is an ongoing process and a system needs to be devised from the beginning of the HACCP plan by LCP, which is suitable for its needs.

Assessment of facilities, determination of PRPs and training requirements

Over and above the action plan, the first need that was identified was that of conducting a closer inspection of the facilities in order to:

- Determine the status of pre-requisite programmes (PRPs) [i.e. Good Manufacturing Practices (GMPs) and Good Hygiene Practices (GHPs)], which are known and accepted to be essential as a base for any HACCP programme;
- Determine the state of the processing facilities, from receiving of the fruit through to dispatching of the final product;
- Determine training requirements of staff, in particular, those to be part of the HACCP team as well as those who will monitor the critical control points (CCPs) identified.

Facilities and PRPs

Findings regarding **facilities and PRPs**, which were taken from a combination of the gap analysis conducted on 4th and 5th March as well as visit conducted on 17th, 18th and 19th March, indicated the following:

- ☞ Although many documented procedures exist, most are outdated and / or confusing, and need to be updated accordingly as well as coordinated into some coherent system;
- ☞ Whilst some work instructions do exist, others do not, such as is the case for certain microbiological methods, which are conducted without written methods in place and without reference to a standard method and without validation of the particular method;
- ☞ Maintenance programmes and procedures for **equipment** and **physical facilities,** such as buildings, roofs, gutters etc are lacking, thus resulting in possible foreign objects landing in the product – this would be due to flaking metal and paint from areas such as improperly maintained equipment, roof tips jutting over conveyor belts conducting fruit to the plant, gutters, pipes etc;
- ☞ Also, pertaining to maintenance, some of the processing facilities have no ceilings in place and hence there is a threat with respect to nesting birds and other insect and rodent activity in the facility;
- ☞ Adequate protective material needs to be placed on the inside of all glass windows to prevent them from shattering into the product, should they break;
- ☞ Considering that portions of the plant have been added over the years without proper planning, flow of product was never taken into consideration, which is not ideal in this situation;
- ☞ Personnel hygiene, specifically personal habits, locker rooms, toilet facilities, handwashing facilities, use of protective clothing, policy for dealing with injuries and communicable diseases as well as procedures for accommodating visitors to the plant, etc need to be addressed as these too are not up to standard;
- ☞ General housekeeping of the plant needs to be upgraded;
- ☞ A policy and procedures regarding waste control need to be written and implemented;

- ☞ Focussed training programmes for workers need to implemented and documented as an important PRP. These training programmes should include personal hygiene practices; correct storage, handling and disposal of chemicals; correct storage and handling of food ingredients; basic food hygiene and its importance re HACCP, etc;
- ☞ A pest control programme is in place, but should be documented specifically as a PRP;
- ☞ Certain practices such as addition of hydrogen peroxide to the initial washing water, in which received fruit is washed, need to be documented in terms of **who, what, when and how;**
- ☞ Certain practices such as washing drums with running water in the same room in which dry food ingredients are stored, need to change;
- ☞ Proper storage and in particular, use of chemicals such as hydrogen peroxide need to be documented and monitored, due to its hazardous nature;
- ☞ Pools of stagnant water were observed throughout the plant, which are an ideal breeding ground for microorganisms. Where necessary, floors need to be restructured to create adequate sloping for run-off of water to avoid the formation of stagnant pools;
- ☞ Soaking smaller pieces of equipment in a bath of sanitizer for long periods of time should be discouraged as sanitizer concentration may decrease with time, thus rendering it ineffective. Microbiological analyses conducted by Prof Anelich on such samples indicated this to be true due to the presence of microbial growth.

All of the above-mentioned “areas of concern” are regarded as PRPs, which need to be addressed **before** HACCP can be implemented, thus still requiring urgent attention. Major progress has been made since the assessment of the plant was submitted to LCP in March 2003, and certain structural, habitual and policy changes have been made. It is also natural and understood that some PRPs will take longer and also need more resources to

rectify, such as buildings and facilities, whilst others such as correcting certain work practices can be more easily and thus, more easily rectified.

Although not part of the scope of work for this project, Prof Anelich decided to assist LCP in documenting PRPs, and ten PRPs were identified as important for LCP. Generic requirements for the following ten PRPs have thus been written:

1. Premises
    - 1.1 Building exterior
    - 1.2 Building interior
    - 1.3 Sanitary facilities
    - 1.4 Water and steam quality and supply
2. Purchasing, transportation and storage
    - 2.1 Suppliers
    - 2.2 Transportation
    - 2.3 Storage
    - 2.4 Mass and Temperature Control
3. Equipment
    - 3.1 General equipment
4. Personnel
    - 4.1 Training
    - 4.2 Hygiene and health
5. Sanitation and pest control
    - 5.1 Sanitation
    - 5.2 Pest control
6. Stock rotation
    - 6.1 Stock rotation programme
7. Good Laboratory Practice
    - 7.1 Microbiological analyses
    - 7.2 Chemical and physical analyses
8. Glass Control

8.1 Glass control programme

9. Recall

9.1 Recall system

10. Customer complaints

10.1 Customer complaint system

Training requirements of management

Considering that LCP has a small management component, the majority of whom have not had any exposure to quality assurance, HACCP etc, Prof Anelich identified a need for an induction session to HACCP and PRPs. A suitable presentation was compiled and presented by Prof Anelich to the management team, including the General Manager, Mr Dunlop, on the morning of 18th March 2003, from 08:30 to 13:00 at LCP premises, even though this was not included in the scope of work. This presentation was attended by eight persons, most of whom will be part of the HACCP team. All participants received a copy of the presentation in the form of a handout. The presentation covered the following issues:

- The difference and relationship between food quality and food safety;
- Foodborne diseases and the concept of **risk** on a global level;
- HACCP – background, origin and advantages;
- Types of hazards with relevant examples;
- The seven principles of HACCP;
- The 12 steps of HACCP (each discussed in detail with relevance to the fruit concentrate industry);
- Relevant definitions such as hazard analysis, critical control point etc;
- HACCP pre-requisites including management's commitment and PRPs (in detail, with reference to relevant examples, definitions and documents);
- Reasons for failure of HACCP;
- Current and future trends, including Eurepgap and Risk Analysis

Training requirements of rest of staff complement at LCP

A “training and awareness” need was identified by LCP and Prof Anelich jointly, for the rest of the staff, which included all administrative and office staff as well as all the workers on all levels. Although not part of the scope of work, a slide presentation entitled “Good Manufacturing and Good Hygienic Practices” was compiled containing 125 slides of photographs taken in the plant of bad manufacturing practices and general lack of hygiene, cleanliness and housekeeping. The above-mentioned staff (approximately 220 people), were divided into five groups and the slide presentation was shown to them separately on 8 April 2003. During this training session, emphasis was placed on the role staff could play in rectifying the situation, thus empowering them to take ownership of maintaining their own facilities and environment.

A more intensive training need on Basic Hygiene was identified for workers in the plant and an outside company with multilingual skills has been approached to present this training.

Relevant documentation

National and International Standards and documents that were used to compile this HACCP plan included:

- SABS 049 – Code of Practice for Food Hygiene Management – this document deals with all the pre-requisites required prior to the implementation of HACCP;
- Codex Alimentarius documents and Food Hygiene texts – these documents deal with PRPs, HACCP principles and steps;
- SABS 0330:1999 Code of Practice: The Implementation and Management of a Hazard Analysis and Critical Control Point (HACCP) System – this standard describes the requirements of the SABS for HACCP certification;
- Juice HACCP plan requirements of the Food and Drug Administration of USA;
- Course work and training documentation compiled and used by Prof Anelich over the years;

- Any other relevant documentation.

HACCP PLAN

The HACCP plan was compiled according to the 12 steps as set out in the Codex Alimentarius and the SABS 0330:1999 Code of Practice. These are:

Step 1: Select the HACCP Team
Step 2: Describe the product
Step 3: Identify the intended use of the product
Step 4: Construct a product flow diagram
Step 5: Arrange on-site confirmation of the flow diagram
Step 6: Conduct a hazard analysis
Step 7: Determine the critical control points (CCPs)
Step 8: Establish target levels and tolerances for each CCP (critical limits)
Step 9: Establish a monitoring system for each CCP
Step 10: Establish corrective action plans
Step 11: Establish verification and review procedures
Step 12: Establish record-keeping and documentation.

All of the above-mentioned steps were conducted according to the Action Plan given in Table 1. Each one of the 12 steps is described in full and all documentation for the completed HACCP plan is included in Annexure A. The necessary records that have been generated and which will be used in the implementation of HACCP are attached as Annexure B.

CONCLUSION

The pre-assessment of the facilities, processes and procedures, in particular, indicated that many PRPs were lacking (section 3.2.1 above). This has caused a significant delay in

implementing PRPs, which are basic necessities, before HACCP can be implemented. However, ten PRPs have been selected, which are pertinent to LCP and generic requirements for these PRPs have been written.

In terms of training, it is clear that the HACCP induction course presented to management was necessary in order to create an awareness of what was expected from everyone on the HACCP team in terms of time and expertise. Emphasis on management's commitment ensured that the General Manager understood his role in the process, especially in terms of making the necessary resources available for the envisaged changes. The slide presentation given to the rest of the staff at LCP on 8th April 2003 (hygiene awareness training) was very well received by all staff and on subsequent visits by Prof Anelich to the plant, major improvements in housekeeping, personal hygiene, the wearing of protective clothing, disposal of waste in the correct receptacles, etc were clearly evident. Further formal training in basic hygiene for all workers has been budgeted for and will be conducted soon.

The HACCP plan has been written (Annexures A & B) by the HACCP team, with the help, guidance and experience of Prof Anelich. Besides being a successful exercise, it was a learning process for all the members of the HACCP team, as the actual impact of HACCP and all its future implications in terms of implementation and management of the HACCP system over time, is only realized when one is involved on a hands-on basis. Herein lies the actual success of HACCP, as the employees of a company must themselves, work through all the 12 steps of HACCP, in order to understand it and to take ownership of the process and the final written plan.

As a direct result of the project, LCP has realized the importance of implementing HACCP as a food safety management tool in order to trade successfully, and has therefore created a new position in the company for a HACCP manager. It is hoped that a suitable appointment will be made by 1st August 2003. The duties of this person will include managing and maintaining the HACCP plan over time, as well as extending the current

HACCP plan to all sections of LCP, as well as to manage its implementation appropriately, in order to ensure continued certification.

Finally, it is well known in food-related circles, that in order for any food company to trade locally and internationally, it is imperative that HACCP is implemented as **the internationally-accepted** food safety management tool. The challenge, however lies in the compilation and implementation of focused and applicable HACCP plans for the various food processing sectors, especially in developing countries, where resources are scarce. It is therefore, particularly relevant and important that projects such as this one be continued in the future to enhance and more especially, to ensure continued trade with other countries, especially in the developed world.

ANNEXURE A

HACCP PLAN FOR THE SUBTROPICAL ASEPTIC PROCESSING PLANT AT LETABA CITRUS PROCESSORS

Prepared by

PROFESSOR L E ANELICH

HACCP Consultant

For

Chemonics International Inc

30 June 2003

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Step 1: Assemble the HACCP Team

The following persons constituted the HACCP team (18 March 2003):

- Paul Corbett (PC) -QA Manager & Chairperson of team
- David Keyser -Production Manager & Technical Secretary
- James Mogg -Maintenance Manager
- Brian Bruce -Warehouse
- Karien Erasmus -Sales Manager

As chairperson of the HACCP team, PC has defined authority for the following:

- Ensuring that the 12 steps of HACCP are followed according to the action plan for the compilation of the HACCP plan;
- Ensuring that the HACCP system is established, implemented and maintained;
- Reporting on the performance of the HACCP system to management for review as a basis for improving the system;
- Authorising and assisting in organising meetings;
- Organising appropriate training.

The role of Prof Anelich was as consultant and therefore, was not included in the HACCP team (decided in accordance with SABS 0330:1999). A meeting of the above team and Prof Anelich was held on the same day and each team member was required to sign a "letter of commitment" which will be filed in the HACCP file. A blank letter of commitment is included on page 5. The scope of reference of the HACCP system was also identified at this meeting. The scope of reference was to cover only fruit purees aseptically processed in the subtropical plant and the HACCP plan would cover food safety as well as wholesomeness issues. The HACCP team was to have regular meetings, keep minutes and agendas of all the meetings and utilize Prof Anelich in her role as consultant for assistance, guidance and experience in implementing HACCP.

The product is to be judged safe and microbiologically wholesome at the point of manufacture, but should undergo further processing by other industrial downstream companies, producing products for the consumer market.

TITLE: HACCP Team Commitment Form	DOCUMENTATION: PAGE 1 of 1
LCP HACCP DOCUMENTATION	REVISION: 1 EFFECTIVE DATE : JULY 2003

LETABA CITRUS PROCESSORS

I, _____, hereby accept to assign and commit myself as a member of the company's HACCP team and to provide the team with the following expertise:

_____

_____

_____

_____

I also commit myself to assisting the team with the compilation, implementation, management, maintenance and review of the HACCP system.

_____ _____

Signature **Date**

Steps 2 & 3: Describe the Product and Identify Intended Use of the Product

Four fruit products were considered. They are:

- Mango puree
- Banana puree
- Guava puree
- Paw-paw puree.

All required specifications of each of these products are given in the following pages in tabulated form.

TITLE: Product Description And Intended Use Statement	DOCUMENTATION: PAGE 1 of 2 REVISION: 1 EFFECTIVE DATE : JULY 2003
LCP HACCP DOCUMENTATION	

PRODUCT NAME: 15°B Mango Puree	
Composition:	Mango Puree
Packaging:	Heat-treated fruit puree, packed aseptically at filling. Aseptic Bags are filled in plastic lined drums and sealed with a tamper evident seal.
Microbicidal/Static Treatments:	=> 102°C minimum depending on product
Storage Conditions:	0 – 10°C (Not to be frozen)
Distribution Conditions:	Product to be distributed according to the temperature requirements of the product.
PHYSICAL SPECIFICATIONS	
Screen size:	0.010 Inches or 0.454mm (Factor 25.4 in to cm)
Taste and odour:	Typical Mango
Texture:	Smooth
Visual colour:	Yellow to Orange
Foreign Matter:	None
Additives:	Citric acid
Shelf Life:	18 Months at 0 – 10°C or 2 Months at ambient temperature (Not exceeding 25°C)
CHEMICAL SPECIFICATIONS	
Brix: (Single strength):	14.0° - 16.0B
PH value:	3.4 – 4.4
Total titratable acid (Single Strength):	0.3 – 0.6
Vitamin C:	Natural
Preservation and adulteration:	None
Pesticide and heavy metal residues:	Conforms to Statutory Requirements
Microbiological Specifications	
Total Aerobic Plate Count:	<30
Yeast and Mould Count:	<30

Heat Resistant spores:	<30
Lactobacillus count:	<30
Packaging Specifications	
Drum:	210Kg net weight green open top, 200l steel drum with lid and clamp, sealed with nut and bolt. Painted on the inside with red oxide paint.
Aseptic bag:	Tamper proof, 2.5 Mega-Rad irradiated bag
Drum Liner:	Blue Plastic liner 75micron
Cardboard Disc:	Top and bottom disc
Labeling specifications	
Lettering:	Each drum is stenciled and/or labeled
Labeling ink:	Permanent and water resistant
Information:	Batch No, Date of Production, Supplier, Drum No, Product Name, Brix, Net weight
INTENDED USE STATEMENT	
Products undergo further processing by other industrial food companies into products for the consumer market. This per se, is therefore, not consumed directly by consumers. Once opened, the product should be refrigerated between 0 – 3°C and processed within 48 hours. The product is destined for both local and international markets.	

TITLE: Product Description And Intended Use Statement	DOCUMENTATION: PAGE 1 of 2 REVISION: 1 EFFECTIVE DATE : JULY 2003
LCP HACCP DOCUMENTATION	

PRODUCT NAME: 20°B Banana Puree	
Composition:	Banana Puree
Packaging:	Heat-treated fruit puree, packed aseptically at filling. Aseptic Bags are filled in plastic lined drums and sealed with a tamper evident seal.
Microbicidal/Static Treatments:	=> 102°C minimum depending on product
Storage Conditions:	0 – 10°C (Not to be frozen)
Distribution Conditions:	Product to be distributed according to the temperature requirements of the product.
PHYSICAL SPECIFICATIONS	
Screen size:	0.020 Inches or 0.508mm (Factor 25.4 in to cm)
Taste and odour:	Typical Banana
Texture:	Smooth texture
Visual colour:	Creamy yellow to pale buff with fine pips
Foreign Matter:	None
Additives:	Citric acid and Ascorbic acid
Shelf Life:	18 Months at 0 – 10°C or 4 Months at ambient temperature (Not exceeding 25°C)
CHEMICAL SPECIFICATIONS	
Brix: (Single strength):	19.5.0° - 22.0°B
PH value:	3.9 – 4.4
Total titratable acid (Single Strength):	0.25 – 0.60
Vitamin C:	Ascorbic acid to prevent browning
Preservation and adulteration:	None
Pesticide and heavy metal residues:	Conforms to Statutory Requirements
Microbiological Specifications	

Total Aerobic Plate Count:	<30
Yeast and Mould Count:	<30
Heat Resistant spores:	<30
Lactobacillus count:	<30
Packaging Specifications	
Drum:	210Kg net weight green open top, 200l steel drum with lid and clamp, sealed with nut and bolt. Painted on the inside with red oxide paint.
Aseptic bag:	Tamper proof, 2.5 Mega-Rad irradiated bag
Drum Liner:	Blue Plastic liner
Cardboard Disc:	Top and bottom disc
Labeling specifications	
Lettering:	Each drum is stenciled and/or labeled
Labeling ink:	Permanent and water resistant
Information:	Batch No, Date of Production, Supplier, Drum No, Product Name, Brix, Net weight, Product Code
INTENDED USE STATEMENT	
Products undergo further processing by other industrial food companies into products for the consumer market. This per se, is therefore, not consumed directly by consumers. Once opened, the product should be refrigerated between 0 – 3°C and processed within 48 hours. The product is destined for both local and international markets.	

TITLE: Product Description And Intended Use Statement	DOCUMENTATION: PAGE 1 of 2 REVISION: 1 EFFECTIVE DATE : JULY 2003
LCP HACCP DOCUMENTATION	

PRODUCT NAME: 8°B Guava Puree	
Composition:	Guava Puree
Packaging:	Heat-treated fruit puree, packed aseptically at filling. Aseptic Bags are filled in plastic lined drums and sealed with a tamper evident seal.
Microbicidal/Static Treatments:	=> 102°C minimum depending on product
Storage Conditions:	0 – 10°C (Not to be frozen)
Distribution Conditions:	Product to be distributed according to the temperature requirements of the product.
PHYSICAL SPECIFICATIONS	
Screen size:	0.010 Inches or 0.454mm (Factor 25.4 in to cm)
Taste and odour:	Typical Guava
Texture:	Smooth slightly gritty
Visual colour:	Pinkish
Foreign Matter:	None
Additives:	None
Shelf Life:	18 Months at 0 – 10°C or 4 Months at ambient temperature (Not exceeding 25°C)
CHEMICAL SPECIFICATIONS	
Brix: (Single strength):	8.0° - 11.0°B
PH value:	3.6 – 4.2
Total titratable acid (Single Strength):	0.25 – 0.85
Vitamin C:	Natural
Preservation and adulteration:	None
Pesticide and heavy metal residues:	Conforms to Statutory Requirements
Microbiological Specifications	
Total Aerobic Plate Count:	<30

Yeast and Mould Count:	<30
Heat Resistant spores:	<30
Lactobacillus count:	<30
Packaging Specifications	
Drum:	210Kg net weight green open top, 200l steel drum with lid and clamp, sealed with nut and bolt. Painted on the inside with red oxide paint.
Aseptic bag:	Tamper proof, 2.5 Mega-Rad irradiated bag
Drum Liner:	Blue Plastic liner 75micron
Cardboard Disc:	Top and bottom disc
Labeling specifications	
Lettering:	Each drum is stenciled and/or labeled
Labeling ink:	Permanent and water resistant
Information:	Batch No, Date of Production, Supplier, Drum No, Product Name, Brix, Net weight
INTENDED USE STATEMENT	
Products undergo further processing by other industrial food companies into products for the consumer market. This per se, is therefore, not consumed directly by consumers. Once opened, the product should be refrigerated between 0 – 3°C and processed within 48 hours. The product is destined for both local and international markets.	

TITLE: Product Description And Intended Use Statement	DOCUMENTATION: PAGE 1 of 2 REVISION: 1 EFFECTIVE DATE : JULY 2003
LCP HACCP DOCUMENTATION	

PRODUCT NAME: 10°B Paw Paw Puree	
Composition:	Paw paw puree
Packaging:	Heat-treated fruit puree, packed aseptically at filling. Aseptic Bags are filled in plastic lined drums and sealed with a tamper evident seal.
Microbicidal/Static Treatments:	=> 102°C minimum depending on product
Storage Conditions:	0 – 10°C (Not to be frozen)
Distribution Conditions:	Product to be distributed according to the temperature requirements of the product.
PHYSICAL SPECIFICATIONS	
Screen size:	0.010 Inches or 0.454mm (Factor 25.4 in to cm)
Taste and odour:	Typical Paw Paw
Texture:	Smooth texture
Visual colour:	Orange to Red
Foreign Matter:	None
Additives:	Citric acid
Shelf Life:	18 Months at 0 – 10°C or 4 Months at ambient temperature (Not exceeding 25°C)
CHEMICAL SPECIFICATIONS	
Brix: (Single strength):	10.0° - 13.0°B
PH value:	3.8 – 4.4
Total titratable acid (Single Strength):	0.25 – 0.50
Vitamin C:	Natural
Preservation and adulteration:	None
Pesticide and heavy metal residues:	Conforms to Statutory Requirements
Microbiological Specifications	

Total Aerobic Plate Count:	<30
Yeast and Mould Count:	<30
Heat Resistant spores:	<30
Lactobacillus count:	<30
Packaging Specifications	
Drum:	210kg net weight green open top, 200l steel drum with lid and clamp, sealed with nut and bolt. Painted on the inside with red oxide paint.
Aseptic bag:	Tamper proof, 2.5 Mega-Rad irradiated bag
Drum Liner:	Blue Plastic liner 75micron
Cardboard Disc:	Top and bottom disc
Labeling specifications	
Lettering:	Each drum is stenciled and/or labeled
Labeling ink:	Permanent and water resistant
Information:	Batch No, Date of Production, Supplier, Drum No, Product Name, Brix, Net weight
INTENDED USE STATEMENT	
Products undergo further processing by other industrial food companies into products for the consumer market. This per se, is therefore, not consumed directly by consumers. Once opened, the product should be refrigerated between 0 – 3°C and processed within 48 hours. The product is destined for both local and international markets.	

Steps 4 & 5: Construct a Product Flow Diagram and On-Site Confirmation of the Flow Diagram

The HACCP team and the consultant began compiling the process flow chart (product flow diagram), on 8 and 9 April 2003, taking all processing steps into account, from receiving of the fruit through to dispatching of the final product. The process flow chart was then confirmed by all members of the HACCP team and the consultant during the May visit to the processing plant. Thereafter, the necessary adjustments were made. The completed flow chart is given as a separate attachment (Appendix I).

Step 6: Conduct Hazard Analysis

The HACCP team began the hazard analysis process together with Prof Anelich in the week of 7-9 April 2003, during an on-site visit by Prof Anelich. Because of the importance of this process, as it is here that potentially important hazards are often missed, the process took some time. Therefore, in the weeks that followed, continuous adjustments were made, until the final analysis was ratified by the team at a meeting with Prof Anelich on 19 June 2003, at LCP's premises. The full hazard analysis is given as a separate attachment (Appendix II).

Step 7: Determine Critical Control Points (CCPs)

The HACCP team, together with Prof Anelich determined the CCPs for each processing step (Appendix I - Process Flow Diagram) during the May 2003 visit to LCP. The CCP decision tree as compiled by Codex Alimentarius was used and is also available in the SABS 0330:1999 Code of Practice. Only one CCP was identified, i.e. thermal processing step. This is in accordance with most HACCP plans for similar products and was therefore, not surprising. In addition, all the PRPs mentioned in the hazard analysis as able to deal with the hazards, must be in place and functioning.

Step 8: Establish Target Levels and Tolerances (Critical Limits)

The critical limits were established and ratified at a HACCP team meeting together with Prof Anelich during the June 2003 visit to LCP.

Step 9: Establish a Monitoring System for each CCP

The monitoring procedure for the only CCP identified was established and ratified at a HACCP team meeting together with Prof Anelich during the June 2003 visit to LCP.

Step 10: Establish Corrective Actions

Corrective actions covering both the disposition of non-conforming product and re-setting of any equipment controls, were determined and ratified at a HACCP team meeting together with Prof Anelich during the June 2003 visit to LCP. All information for steps 7-10, are given in the table entitled “CCPs, critical limits, monitoring and corrective actions”, found on the following page of this document.

TITLE: HACCP Plan Form – CCPs, critical limits, monitoring actions and corrective actions	DOCUMENTATION: PAGE 1 of 1 REVISION: 1 EFFECTIVE DATE : JULY 2003
LCP HACCP DOCUMENTATION	

Process step	CCP	Hazard description	Critical limits	Monitoring procedures					Corrective actions	
				What	How	When	Who	Record	Actions	Record
Thermal processing	Yes	Microbial survival due to insufficient temperature and/or holding time	Temperature not less than 102 EC / 60 sec	Temperature /time graph	Visually	Daily	Supervisor	Form xxx is completed by supervisor and signed by production manager	-Isolate and label deviated product with yellow HOLD sticker, refrigerate or freeze -Pasteurizer is resterilized before next batch is heated -Production manager and Quality Assurance Manager decide when deviated product is reworked	Supervisor completes Form yyy for corrective actions and form is signed by production manager

Step 11: Establish Verification and Review Procedures

Verification and review procedures were established and ratified at a HACCP team meeting together with Prof Anelich during the June 2003 visit to LCP. These procedures are found on the following three pages.

TITLE: HACCP Plan Form: Verification and Review Procedures	DOCUMENTATION: PAGE 1 of 3
LCP HACCP DOCUMENTATION	REVISION: 1 EFFECTIVE DATE : JULY 2003

1. Verification procedures

Verification is done by the entire HACCP team to ensure that the CCP(s) identified are valid and effective i.e. that the target levels and tolerances (critical limits) chosen, monitoring and corrective actions are appropriate to ensure food safety. Verification therefore indicates whether the actual HACCP plan is effective in combating the identified food safety issues(s) and whether the practical application of all HACCP procedures (i.e. HACCP study) is in compliance with the documented HACCP procedures as given in the HACCP plan.

Verification of CCP i.e. Thermal Processing

1. Evaluate the temperature and time checking procedure (monitoring):
   - 1.1 Check the temperature probe calibration records according to actions spelt out in GMP no. …..
   - 1.2 Temperature and time checking method on graph paper
   - 1.3 Check frequency of checking method
2. Evaluate CCP records for:
   - 2.1 Correct completion of monitoring records
   - 2.2 Any deviations that actually occurred
   - 2.3 Evaluate microbiological results
3. Evaluate corrective actions for:
   - 3.1 Correct execution of corrective actions as documented in the HACCP plan, once monitoring has shown that the CCP is out of control

3.2 Correct completion of corrective action records

4. How frequently was CCP out of control?
5. Is there a specific pattern regarding point 4 e.g. time of day, type of product?
6. What were the reasons for CCPs being out of control e.g. low temperatures, wrong times?
7. Any customer complaints recorded, during these periods where CCP was out of control and product was reworked?
8. Any customer complaints recorded regarding product that was deemed in control and subsequently released?
9. Validate the CCP target level (critical limit)
10. Complete the Verification Record (……..)

Frequency of verification

Initially, verification will be conducted every month for a period of at least 3 months; thereafter once every 3 months.

Filing location

Verification file

2. Review procedures

Reviewing a HACCP plan is done according to a schedule to ensure its **effectiveness** and its **improvement.** A review will be automatically triggered if verification shows that the system is undergoing a major failure, as well as before any changes in operations that might compromise food safety, are implemented. Review of the HACCP plan is management's responsibility.

HACCP review meeting

Management, together with the HACCP team, will conduct HACCP review meetings, according to a specific agenda. HACCP Plan Review Record …. Must be completed, which indicates any major changes made to the HACCP plan.

Frequency of meetings

A HACCP review meeting must take place after every verification procedure, hence once per month for three months, initially and thereafter, once every three months. A HACCP review will automatically be triggered should / when any of the following conditions occur:

a) At the beginning of each fruit processing season
b) A change in product formulation
c) A change in the processing system
d) A change in the factory layout and environment
e) A modification to the processing equipment
f) A change in the cleaning and sanitizing programme
g) A change in the packaging, storage and distribution system
h) Changes to staff levels and responsibilities
i) Any report from the market place that indicates a health or spoilage risk associated with the product
j) An anticipated change in consumer use
k) Statutory changes.

Filing location

HACCP Review meetings: HACCP Review Meetings File
HACCP Plan Reviews: HACCP Review File

STEP 12: Establish Record-keeping and Documentation

Each document and record will contain a header giving at least the following details:

1. Company name
2. Title of the document / record
3. Number of the document / record
4. Revision number of the document
5. Date of implementation
6. Page numbering in the format: Page X of Y

Each document that becomes part of the HACCP file will be signed by the assigned person, who is the Quality Assurance Manager at this point in time. A Master File containing a hard copy of the document will be kept in the office of the Quality Assurance Manager. All records that are completed on a daily basis will be kept in a separate file and will be filed daily. This file shall also be kept in the office of the Quality Assurance Manager. All HACCP documentation and blank records shall also be made available on the Web Site established for the company, LCP. However, only the Quality Assurance Manager shall have access to the editing option for all these documents and records, in order to ensure continuity. Furthermore, regular back-ups will be made and kept by the Quality Assurance Manager.

ANNEXURE B

LIST OF RECORDS COMPILED FOR THE HACCP PLAN FOR LETABA CITRUS PROCESSORS

Prepared by

PROFESSOR L E ANELICH
HACCP Consultant

For

Chemonics International Inc

30 June 2003

TABLE OF CONTENTS

INTRODUCTION

This annexure contains records that were specifically generated for this HACCP plan. The records are an essential part of the daily running of HACCP, as all activities surrounding the CCP (thermal processing in this case) need to be noted on a daily basis, by appropriate persons assigned to these activities. These records provide the verification and reviewing teams with the evidence required in order to make informed decisions regarding any changes that need to made to the HACCP plan, thus ensuring its success.

Records included in this annexure are:

1. Monitoring Action Record;
2. Corrective Action Record;
3. Verification Record;
4. Review Record.

TITLE: Monitoring Action Record	DOCUMENTATION: PAGE 1 of 1
LCP HACCP DOCUMENTATION	REVISION: 1 EFFECTIVE DATE : JULY 2003

Date:
Time:
Product type:
Batch number:
Person monitoring:
Visual inspection of temperature and time charts:
Frequency of monitoring: Daily
CCP in control? Yes No
Comments:

Supervisor

Production Manager

TITLE: Corrective Action Record	DOCUMENTATION: PAGE 1 of 1
LCP HACCP DOCUMENTATION	REVISION: 1 EFFECTIVE DATE : JULY 2003

Date:
Time:
Product type:
Batch number:
Completed by:
Description of deviation, including cause:
Corrective action taken:
Corrective action for elimination of re-occurrence of problem and identify training needs:

Supervisor

Production Manager

TITLE: Verification Record	DOCUMENTATION: PAGE 1 of 1
LCP HACCP DOCUMENTATION	REVISION: 1 EFFECTIVE DATE : JULY 2003

Date:	
Conducted by (list all members of meeting):	
Description of findings:	
Recommendation:	
By:	Position:
Corrective action (including preventive action when applicable):	
Responsible person:	Target date:
Corrective action follow-up / verification:	
Responsible person:	Target date:

TITLE: Review Record	DOCUMENTATION: PAGE 1 of 1
LCP HACCP DOCUMENTATION	REVISION: 1 EFFECTIVE DATE : JULY 2003

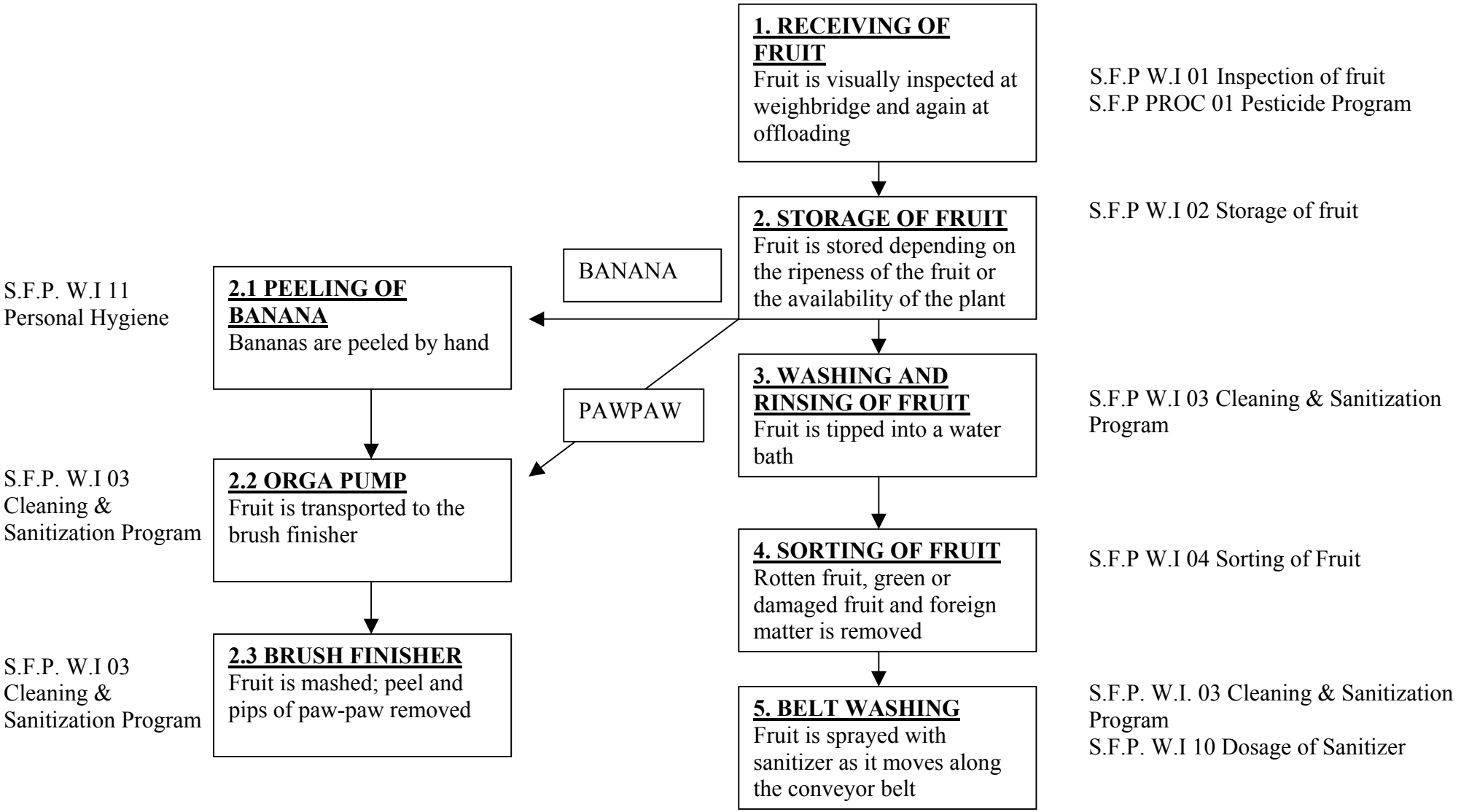
Date:
Completed by:
Position:
Reason for review (any of below): 1. Scheduled review 2. The beginning of a new fruit processing season 3. A change in product formulation 4. A change in the processing system 5. A change in the factory layout and environment 6. A modification to the processing equipment 7. A change in the cleaning and sanitizing programme 8. A change in the packaging, storage and distribution system 9. Changes to staff levels and responsibilities 10. Any report from the market place that indicates a health or spoilage risk associated with the product 11. An anticipated change in consumer use 12. Statutory changes
List major changes made to HACCP plan:

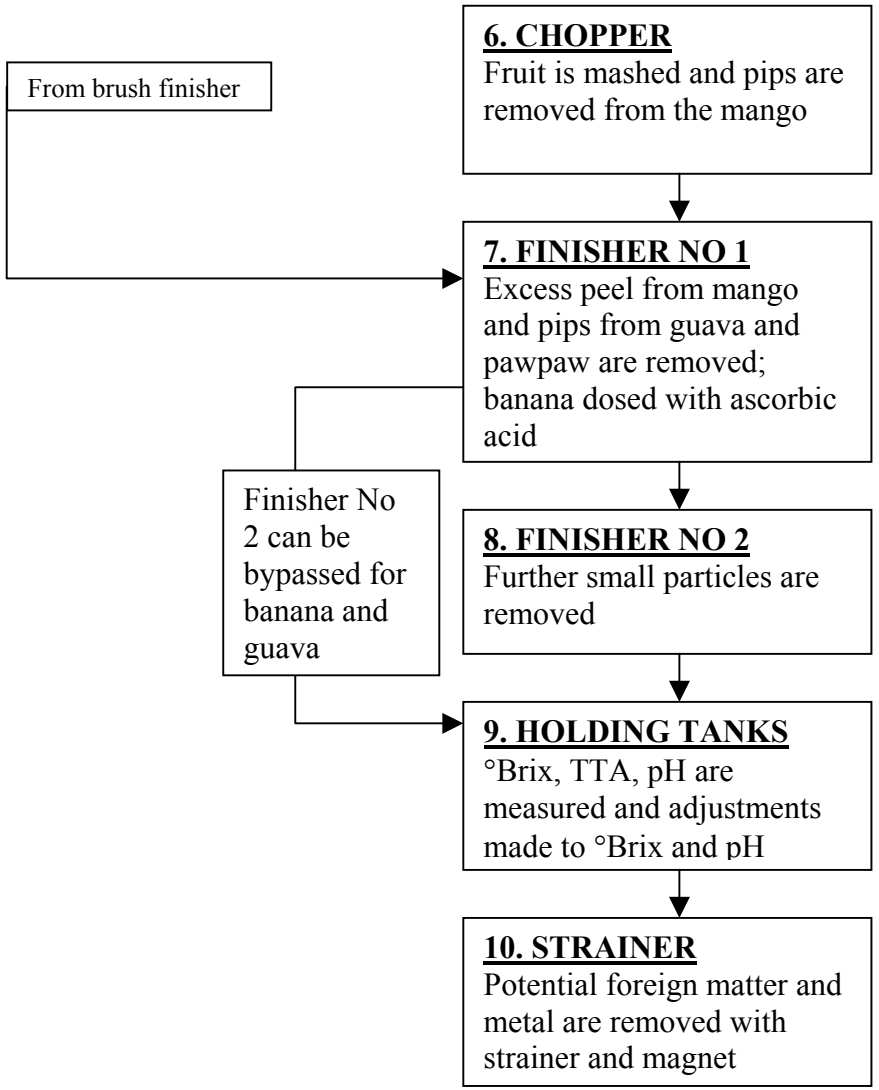
Signature of HACCP Team Leader Date:

APPENDIX I to Annexure A
(HACCP PLAN REPORT)

PROCESS FLOW DIAGRAM - LCP

30 June 2003


1. RECEIVING OF FRUIT
Fruit is visually inspected at weighbridge and again at offloading
S.F.P W.I 01 Inspection of fruit
S.F.P PROC 01 Pesticide Program
2. STORAGE OF FRUIT
Fruit is stored depending on the ripeness of the fruit or the availability of the plant
S.F.P W.I 02 Storage of fruit
BANANA
PAWPAW
2.1 PEELING OF BANANA
Bananas are peeled by hand
S.F.P. W.I 11
Personal Hygiene
2.2 ORGA PUMP
Fruit is transported to the brush finisher
S.F.P. W.I 03
Cleaning & Sanitization Program
2.3 BRUSH FINISHER
Fruit is mashed; peel and pips of paw-paw removed
S.F.P. W.I 03
Cleaning & Sanitization Program
3. WASHING AND RINSING OF FRUIT
Fruit is tipped into a water bath
S.F.P W.I 03 Cleaning & Sanitization Program
4. SORTING OF FRUIT
Rotten fruit, green or damaged fruit and foreign matter is removed
S.F.P W.I 04 Sorting of Fruit
5. BELT WASHING
Fruit is sprayed with sanitizer as it moves along the conveyor belt
S.F.P. W.I. 03 Cleaning & Sanitization Program
S.F.P. W.I 10 Dosage of Sanitizer



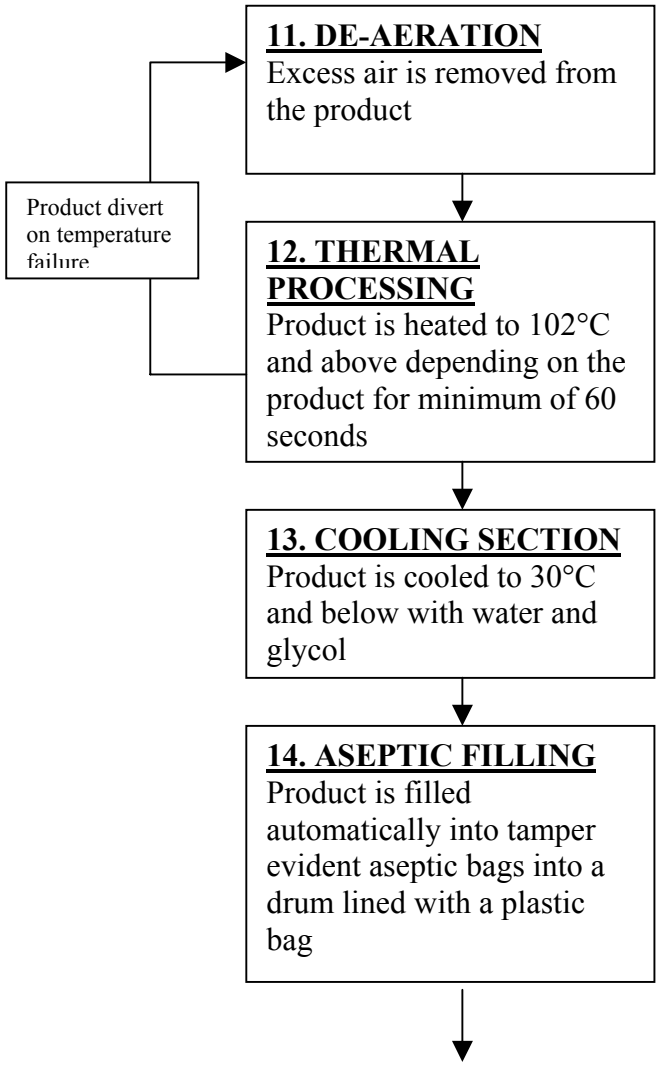
S.F.P W.I 05 Operation of the subtropical plant
S.F.P W.I 03 Cleaning & Sanitization Program

S.F.P W.I 05 Operation of the subtropical plant
S.F.P W.I 03 Cleaning & Sanitization Program
S.F.P. W.I 12 Ascorbic acid dosage

S.F.P W.I 05 Operation of the subtropical plant
S.F.P W.I 03 Cleaning & Sanitization Program

S.F.P W.I 06 Analysis of Puree for °Brix, TTA, pH and correction of °Brix and pH

S.F.P W.I 03 Cleaning &Sanitization Program



S.F.P W.I 07 Operation of the Aseptic Plant

S.F.P W.I 07 Operation of the Aseptic Plant

S.F.P W.I 07 Operation of the Aseptic Plant

S.F.P W.I 08 Drum Filling and Stencilling

15. STORAGE OF DRUMS
Palletise according to instruction; store within 4 hours at 0 – 10°C

S.F.P W.I 09 Storage of drums

↓

16. RELEASE AND DISTRIBUTION
Product is released according to procedure and distributed in refrigerated trucks

Q.A PROC 01 Product approval Procedure
W.H PROC 01 Distribution Procedure

APPENDIX II to Annexure A (HACCP PLAN REPORT)

HAZARD ANALYSIS - LCP

30 June 2003

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 1 Receiving of fruit	Chemical	Pesticide residue and/or inadequate holding periods between spraying and harvesting	No	Likely	Moderate	Yes	Pesticide residues are regarded as a health hazard to human beings	Random sampling to test for pesticide residues (GMP… WI…); Spray programs submitted by suppliers (SFP Proc 01).; Traceability between raw material supplier and end product
	Physical	Sand, Stones, Pests, Wood	No	Likely	Moderate	Yes	People can choke on foreign objects and injure their mouths. Presence of pests renders product unfit for human consumption	Visual inspection upon receiving and weighing – unfit fruit is rejected (GMP…SFP WI 01); Washing, rinsing and sorting before processing (GMP…SFP WI 04); Screens downstream
	Microbiological	Presence of microorganisms	No	Likely	Moderate	Yes	High microbial load may lead to possible spoilage of finished product	Visual inspection, washing, rinsing and sorting prior to processing (GMP…&…; SFP WI 01 & 04); Thermal treatment downstream

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 2 Storage of fruit	Chemical	None						
	Physical	Sand, stones, wood etc	No	Likely	Moderate	Yes	People can choke on foreign objects and injure their mouths. Presence of pests renders product unfit for human consumption	Washing, rinsing and sorting before processing (GMP… SFP WI 04); Screens downstream
	Microbiological	Microbial growth and cross contamination between fruits making contact with each other	No	Likely	Moderate	Yes	High microbial load may lead to possible spoilage of product	Maintain ideal storage conditions (GMP…SFP WI 02); Thermal processing downstream
Step 2.1 Peeling of banana	Chemical	None						
	Physical	Jewellery and other personal effects	Yes			No		GMP for personnel hygiene (SFP WI…..); GMP for protective clothing
	Microbiological	Microbial cross contamination from hands of workers	Yes			No		GMP for personnel hygiene (SFP WI…)

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 2.2 Orga pump	Chemical	None						
	Physical	Pieces of metal from equipment into product	No	Unlikely	Low	Yes	Considered a hazard, although probability is unlikely that pieces of metal could land in the product as has been indicated from past experience	GMP for maintenance; Screens and magnet downstream will remove debris
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03)
Step 2.3 Brush finisher	Chemical	None						
	Physical	Bristles breaking off and landing in product	No	Likely	Low	Yes	Bristles would not be particularly dangerous to human health but are nevertheless undesirable in the product	Screens downstream would adequately deal with this hazard
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03)

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 3 Washing and rinsing	Chemical	Chemical quality of water;	Yes			No		Regular testing for chemical quality of water, in-house and by accredited laboratory;
	Physical	None						
	Microbiological	Microbial cross contamination due to fruits coming into contact with one another; microbiological quality of water	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03); Thermal processing downstream; Regular testing for microbiological quality of water, in-house and by accredited laboratory
Step 4 Sorting the fruit	Chemical	None						
	Physical	None						
	Microbiological	Microbial growth and cross contamination due to unclean equipment and hands of workers	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03); GMP for personnel hygiene (SFP WI…); Sorting of fruit (SFP WI 04)
Step 5 Belt washing	Chemical	Chemical quality of water; Excess sanitizer	Yes Yes			No No		Regular testing for chemical quality of water, in-house and by accredited laboratory; Correct dosing of sanitizer to washing water (GMP… SFP WI…)
	Physical	None						

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

	Microbiological	Microbial cross contamination from unclean equipment and quality of water	Yes			No		Correct dosing of sanitizer to washing water (SFP WI…); GMP for cleaning and sanitizing equipment (SFP WI 03); Regular testing for microbiological quality of water, in-house and by accredited laboratory
Step 6 Chopper	Chemical	None						
	Physical	Pieces of metal from equipment into product	No	Unlikely	Low	Yes	Considered a hazard, although probability is unlikely that pieces of metal could land in the product as has been indicated from past experience	GMP for maintenance; Screens and magnet downstream will remove debris
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03)

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 7 Finisher No1	Chemical	Overdosing with ascorbic acid	Yes			No		WI .. for correct dosing with ascorbic acid according to specifications; Every batch tested with appropriate kits
	Physical	Broken screen causing metal falling into product	No	Unlikely	Low	Yes	Considered a hazard, although probability is unlikely that pieces of metal could land in the product as has been indicated from past experience	GMP for maintenance; Screens and magnet downstream will remove debris
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03)
Step 8 Finisher No 2	Chemical	None						
	Physical	Broken screen causing metal falling into product	No	Unlikely	Low	Yes	Considered a hazard, although probability is unlikely that pieces of metal could land in the product as has been indicated from past experience	GMP for maintenance; Screens and magnet downstream will remove debris
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03)

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 9 Holding Tanks	Chemical	Chemical quality of water; Caustic or sanitizer residue	Yes Yes			No No		Regular testing for chemical quality of water, in-house and by accredited laboratory; SFP WI 05 Operation of Aseptic Plant
	Physical	Foreign matter falling into juice while sampling	Yes			No		GMP for personnel hygiene; SFP WI …for correct sampling procedure
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		SFP WI 05 Operation of Aseptic Plant ; SFP WI ….. for correct sampling procedure
Step 10 Strainer	Chemical	None						
	Physical	None						
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		GMP for cleaning and sanitizing equipment (SFP WI 03)
Step 11 De-aerator	Chemical	Caustic or sanitizer residue	Yes			No		SFP WI 05 Operation of Aseptic Plant
	Physical	None						
	Microbiological	Microbial cross contamination due to unclean equipment	Yes			No		SFP WI 05 Operation of Aseptic Plant

Unlikely Low
Likely Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 12 Thermal processing	Chemical	Caustic or sanitizer residue	Yes			No		SFP WI 05 Operation of Aseptic Plant
	Physical	None						
	Microbiological	Microbial survival due to insufficient temperature and/or holding time	No	Unlikely	Moderate	Yes	If product is not heat-treated at the correct temperature and/or time, microorganisms which could cause spoilage of product may survive	SFP WI 05 Operation of Aseptic Plant; GMP for maintenance; Divert set at 101 °C for recycling of product; GMP for calibration of equipment
Step 13 Cooling section	Chemical	Caustic or sanitizer residue	Yes			No		SFP WI 05 Operation of Aseptic Plant
	Physical	None						
	Microbiological	None						
Step 14 Aseptic filling	Chemical	Caustic and sanitizer residue Low Brix	Yes Yes			No No		SFP WI 05 Operation of Aseptic Plant; SFP WI 06 for analysis of puree for °Brix, TTA, pH
	Physical	Change in colour due to overheating of product	Yes			No		SFP WI… for analysis of colour of product; GMP for calibration of equipment
	Microbiological	Microbial contamination due to bag being torn at bung and due to inadequate CIP	Yes			No		SFP WI 05 Operation of Aseptic Plant; SFP WI….for visual inspection of bags at filling

Unlikely — Low
Likely — Moderate
High

Flow Chart; Operational Steps	Causes of hazards	Potential hazards	Can GMP/GHP adequately control the hazard?	Is this hazard significant?		YES/ NO	Justification	Preventive measures
				Probability	Severity			

Step 15 Storage of drums	Chemical	None						
	Physical	None						
	Microbiological	Microbial contamination due to damage of drums which may lead to puncturing of bags; microbial growth due to inadequate storage conditions	Yes			No		GMP for storage and warehousing and SFP WI 09 for storage of drums
Step 16 Release and distribution	Chemical	None						
	Physical	None						
	Microbiological	Microbial growth due to inadequately refrigerated trucks during transport	Yes			No		GMP for transportation of product and WH Proc 01 for distribution procedure

Unlikely Low
Likely Moderate
High